UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,666	06/20/2007	Dan Rottenberg	372/05298	4703

67801 7590 03/28/2008

MARTIN D. MOYNIHAN d/b/a PRTSI, INC.
P.O. BOX 16446
ARLINGTON, VA 22215

EXAMINER	
SU, SUSAN SHAN	
ART UNIT	PAPER NUMBER
4193	
MAIL DATE	DELIVERY MODE
03/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/597,666	ROTTENBERG ET AL.	
	Examiner	Art Unit	
	SUSAN SU	4193	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 August 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Art Unit: 4193

DETAILED ACTION

Priority

1. Priority claimed of PCT/IL05/000131 filed on 02 March 2005, which claims benefit of Provisional Application 60/573,378 filed on 24 May 2004 is acknowledged. However, priority claimed of Provisional Application 60/541,267 filed 03 February 2004 is not entered because it is more than one year before the filing of the PCT application.

Specification

2. 35 U.S.C. 112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification is replete with terms which are not clear, concise and exact. The specification should be revised carefully in order to comply with 35 U.S.C. 112, first paragraph. Examples of some unclear, inexact or verbose terms used in the specification are:

In paragraph [036] defines that DPRD 101 includes FRM 108 and shunt 107 and control mechanisms 110. Figs. 1B-1I show embodiments of the entire DPRD 101 (which includes shunts, FRM, and control mechanisms such as springs and wires) but are described in the specification as being different embodiments of FRM 108. It is suggested by the examiner that the numbering of the same features should be given the same number, such as "shunt 122" should be changed to --shunt 107-- or --shunt 107B-- (where the letter corresponds to the numbering of the figure to distinguish between the different embodiments).

In paragraph [048] there is a conflict in the numbering of the features: "FRM 108 may include ... flow regulation mechanism 175." It is interpreted by the examiner that --FRM 108 may include ... cap 175.--.

Claim Objections

3. Claims 6, 11, and 17-20 are objected to because of the following informalities:

For claim 6: grammatical error, "said control mechanism i includes" should be changed to --said control mechanism includes--;

For claim 11: spelling error, "said adjustable flow regulation mechanism" should be changed to --said adjustable flow regulating mechanism--;

For claim 17 (and its dependent claims 18-20): grammatical error, "two or more lumens in t a said body" should be changed to --two or more lumens in said body--;

For claim 19: spelling error, "lumens" should be changed to --lumen--.

Appropriate correction is required.

Double Patenting

4. Claims 11-16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11-16 of copending Application No. 11/048,807. Although the conflicting claims are not identical, they are not patentably distinct from each other because all limitations of claims 11-16 of the instant application are claimed in the copending application: a shunt positioned between chambers of the heart, an adjustable flow regulating mechanism, and a control mechanism. The copending application further claims that the control mechanism is adapted for manual control. The instant application claims a broader invention and is therefore an obviousness-type double patenting over the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Wolf et al. (U.S. PGPub 2002/0165606).

With regard to claim 1, Wolf et al. (hereinafter Wolf) teach a differential pressure regulating device (embodiments of the entire device are depicted in Figs. 2-4), the device comprising a shunt (12) being positioned between two or more lumens in a body (see Figs. 1A & 1B where the lumens are clearly labeled left ventricle "LV" and coronary artery "CA"), to enable fluids to flow between said lumens (see [0030] line 3), and an adjustable flow regulating mechanism (10, can be any of the disclosed types such as "flapper valve," ball valve, rigid leaflets, flexible shunt wall that narrows by external pressure), being configured to selectively cover an opening of said shunt, to regulate the flow of fluid through said shunt in relation to a pressure difference between said body lumens (see [0042] lines 5-6).

With regard to claim 2, Wolf also teaches that the flow regulating mechanism (10) is to allow a continuous flow of fluids (inherent when 10 is open) between said body lumens.

With regard to claim 3, Wolf also teaches that the flow regulating mechanism is to be continually adjustable in accordance with at least one pressure threshold ([0053] lines 1-8 discloses that the opening of the conduit varies based on the different parts of the cardiac cycle where the pressure also changes).

With regard to claim 4, Wolf also teaches that the flow regulating mechanism is continually adjustable in accordance with changes in pressure difference between said lumens ([0050]). There is an inherent change in pressure difference accompanying the electrical signal of heart muscle cells in a cardiac cycle.

With regard to claim 5, Wolf also teaches a control mechanism (30 & 36, Fig. 7); to remotely control said flow regulating mechanism (the sensors 30 are placed away from the flow regulating mechanism 10).

With regard to claim 6, Wolf also teaches that said control mechanism includes one or more mechanisms selected from the group consisting of wires, lines, springs, pins, cables, magnets, hooks, latches, electric mechanisms (30), pressure transducers, telemetry mechanisms, wireless mechanisms, pneumatic mechanisms, and motors.

With regard to claim 7, Wolf also teaches that the body lumens are chambers of the heart ([0037] teaches that the shunt is in the "heart wall" where "heart wall" can be interpreted to be an interatrial septum as disclosed in [0029]).

With regard to claim 8, Wolf also teaches that the shunt is to be positioned in the septum of the heart, between the left atrium of the heart and the right atrium of the heart ([0037] teaches that the shunt is in the "heart wall" where "heart wall" can be interpreted to be an interatrial septum as disclosed in [0029]).

With regard to claim 9, Wolf also teaches that the flow regulating mechanism is to close the opening of the shunt ([0050] line 3).

With regard to claim 10, Wolf also teaches that the flow regulating mechanism (10) includes a leaflet valve (see Fig. 7), which is selected from the group in the claim.

With regard to claim 11, Wolf teaches a differential pressure regulating device (embodiments of the entire device are depicted in Figs. 2-4), the device comprising a shunt (12) being positioned between two or more chambers in a heart (see [0037] teaches that the shunt is in the "heart wall" where "heart wall" can be interpreted to be an interatrial septum as disclosed in [0029]), to enable fluids to flow between said chambers (see [0030] line 3); an adjustable flow regulating mechanism (10), being configured to selectively cover an opening of said shunt, to regulate the flow of fluid through said shunt; and a control mechanism (30 & 36, Fig. 7) to be coupled to said adjustable flow regulating mechanism, to remotely activate (the sensors 30 are placed away from the flow regulating mechanism 10) said adjustable flow regulating mechanism.

With regard to claim 12, Wolf also teaches that said control mechanism includes one or more mechanisms selected from the group consisting of wires, lines, springs, pins, cables, magnets, hooks, latches, electric mechanisms (30), pressure transducers, telemetry mechanisms, wireless mechanisms, pneumatic mechanisms, and motors.

With regard to claim 13, Wolf also teaches that said chambers are atriums of the heart ([0037] teaches that the shunt is in the "heart wall" where "heart wall" can be interpreted to be an interatrial septum as disclosed in [0029]).

With regard to claim 14, Wolf also teaches that said chambers are atriums of the heart ([0037] teaches that the shunt is in the "heart wall" where "heart wall" can be interpreted to be an interatrial septum as disclosed in [0029]).

With regard to claim 15, Wolf also teaches that the flow regulating mechanism is to be continually adjustable in accordance with at least one pressure threshold ([0053] lines 1-8 discloses that the opening of the conduit varies based on the different parts of the cardiac cycle where the pressure also changes).

With regard to claim 16, Wolf also teaches that the flow regulating mechanism is rigid (the valves shown in Fig. 7 can be valve 16 which is made of the same material as shunt 12, see [0041 lines 7-9 and [0045] line 7) and its position is directly controlled by the control mechanism (30 & 36 in Fig. 7), thereby substantially determining the precise size of the opening of the shunt.

With regard to claim 17, Wolf teaches an in-vivo pressure control method, the method comprising implanting a differential pressure regulation device in a body (seen in Fig. 1A), said pressure regulation device including a shunt placed between two or more lumens in said body ([0037]), deploying a flow regulating mechanism (since the flow regulating mechanism 10 is either incorporated into 12 during manufacturing or attached after 12 is put into place, see [0043] & [0045]), and controlling said flow regulating mechanism setting according to changes

in pressure differences between said lumens ([0050]). There is an inherent change in pressure difference accompanying the electrical signal of heart muscle cells during a cardiac cycle.

With regard to claim 18, Wolf also teaches remotely controlling said flow regulating mechanism positioning ([0050]).

With regard to claim 19, Wolf also teaches reducing a pressure difference between a first lumen and a second lumen (pressure difference is inherently reduced when blood is allowed to flow freely between the two lumens).

With regard to claim 20, Wolf also teaches positioning said flow regulation mechanism to enable a continual flow of fluid between said lumens ([0050] where there is a continual flow of fluid when the valve 10 is kept open).

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Campbell (U.S. Patent 6,638,303) teaches a heart valve prosthesis with rigid leaflets and a biasing mechanism that is sensitive to fluid pressure.

Smith (U.S. Patent 4,979,955) teaches a power-assisted prosthetic heart valve that utilizes electromagnetic force to slowly close the valve to prevent hemolysis of red blood cells.

Arnold (U.S. Patent 4,995,857) teaches a left ventricle assist device that provides a shunt from the left atrium directly into the arterial system wherein the flow volume is controlled dependent on the fluid pressure in the left atrium.

Carpentier et al. (U.S. Patent 6,039,759) teach a prosthetic mechanical valve with magnets for controlling the movements of the rigid leaflets and to minimize the noise of opening and closing of the valve.

Chang (U.S. Patent 4,601,309) teaches a dash-pot valve so that the closing of the valve is progressively slowed for reducing noise and preventing hemolysis.

Art Unit: 4193

Douglas (U.S. Patent 5,662,711) teaches an apparatus for treating congenital heart defects which includes a shunt with an adjustable flow restrictor.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN SU whose telephone number is (571)270-3848. The examiner can normally be reached on M-F 8:30AM-6:00PM EST (alternate Fridays off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long T. Nguyen can be reached on 571-272-1753. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

S.S.

/Long Nguyen/
Supervisory Patent Examiner
Art Unit 4193